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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,729	05/04/2001	Jen-Kuei Liu	RDID0070US	8090

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EXAMINER	
SCHEINER, LAURIE A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/849,729	Applicant(s) Lui et al.
	Examiner Laurie Scheiner	Art Unit 1648

-- The MAILING DATE of this communication appears on th cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 30, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, and 5-13* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3 and 4* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-13 are pending in this application.

Claims 1, 2 and 5-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7. Claims 3 and 4 are considered below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have not complied with 37 CFR 1.821(d) which requires reference to the sequence that is set forth in the "Sequence Listing" by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims. For instance, claim 3 recites "...nucleotide sequence shown in FIG. 1..." yet fails in reciting the corresponding sequence identifier.

It is noted that SVII should be written out as "sentinel virus II (SVII)" the first time it appears in any claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to "selectively hybridizable" and/or "polynucleotide encoding a SVII. . . fragment" appropriate statistical documentation should be provided and the following terms should be employed: a level or degree of similarity/identity; an alignment with optimized similarity; a percentage of positional identity in an alignment; the probability associated with a particular alignment, etc. Also, the sequence length is critical for determining hybridization of complement. Moreover, sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. The calculation of "similarity" is also affected by variables such as the relative weight given to sequence gaps versus mismatches. Since no art-recognized convention exists regarding the calculation of percent homology, the understanding in the art that the variant would selectively hybridize does not make the claim definite since the length and structure of that which is claimed is unknown. A small nucleotide sequence may share 100% sequence similarity whereas the entire genome containing said small nucleotide sequence may have an overall very low identity percentage.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule as set forth in the sequence identifier corresponding to FIG. 1, does not reasonably provide enablement for a polynucleotide encoding a fragment or a polynucleotide which is selectively hybridizable with said sequence identifier. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The skilled artisan cannot reasonably practice the invention since the scope of the claims is broader than the provided enablement. The disclosure fails to provide any guidance concerning nucleotide sequences of the fragments; what are the precise nucleotide sequences of the fragments? Again, in its precise biological meaning "hybridizable" asserts a type of relationship between two or more things. Thus, similarity, identity and hybridizable are quantitative properties. The specification clearly fails to provide enablement for one of skill to make and use fragments of the nucleotide sequence as represented in FIG 1. Similarly, the specification clearly fails to provide enablement for nucleic acid molecules hybridizable to a sequence that is set forth in FIG. 1. What hybridization conditions are envisaged? The hybridization parameters can vary considerably, even under "standard conditions". A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration, and salt concentration. Again, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. While enablement can be supported even if some experimentation is required, such experimentation must be merely routine and if the results to be obtained are unpredictable the experimentation is not routine, but rather **undue**. Thus, beyond the mere presentation of sequence data for a single nucleic acid molecule, applicants have provided little or no guidance which would, without **undue** experimentation, enable one of ordinary skill in the art to determine what positions, if any, in the nucleic acid molecules are

tolerant to change, the nature and extent of changes that can be made and tolerated in the various positions and what utility will be possessed by the modified molecules(s), particularly in view of the virtually infinite number of compounds encompassed by these claims wherein the molecule can include any number of addition, deletions or substitutions. Without such guidance, the changes which can be made in the proteins structure and still maintain activity/ utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen,* 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim,* 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 3 and 4 are drawn toward a polynucleotide selectively hybridizable with the polynucleotide sequence of FIG. 1. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not

be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.,* 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.,* 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll,* 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga,* 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly,* 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano,* 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell,* 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). The significance of conception and reduction to practice was further addressed by the court in *Fiers v. Sugano* where it was emphasized that "[c]onception is a question of law, reviewed *de novo* on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility." Thus, the courts have emphasized that the inventor must clearly and unambiguously identify the salient characteristics and properties of any given claimed nucleotide sequence. It is not sufficient to provide a vague reference to the biological activity (or specificity) of any given nucleotide sequence or merely a generic method of obtaining it.

Applicant's disclosure fails to provide adequate written support for the invention as claimed. That is, applicant's claims encompass a polynucleotide of virtually any length and/or structure so long as they are selectively hybridizable, or encodes any SVII peptide. Thus, the claimed polynucleotides may differ in overall length, however, the disclosure provides discussion of the viral genome having the sequence set forth by SEQ ID NO:1. As such, the disclosure fails

to provide an adequate written description for subject matter as claimed. The examiner contends that one of skill cannot reproduce that which has not been described. That is, it is evident that applicants were not in possession of that which is claimed at the time of the invention. It is well settled that the claimed subject matter need not be supported by an explicit, word for word recitation, but something more than a suggestion is needed to satisfy the requirement for an adequate written description. As set forth in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

It is the disclosures of the applications that count. Entitlement to a filing date extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. Rather, a[n]... application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought... [A]ll that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention... One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . Although the exact terms need not be used in haec verba, . . . the specification must contain an equivalent description of the claimed subject matter. [Citations omitted]

It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application must describe the claimed features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can

normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

Laurie Scheiner/LAS
September 26, 2003

LAURIE SCHEINER
PRIMARY EXAMINER